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10/825,359	04/16/2004	Peter Gibson	22409-00107-US	8104

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EXAMINER
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HOLMES, REX R

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3762

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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patent@cblh.com



## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102/103***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 4, 7-9, 14, 20, 24, 27-28, 30-31, 89-93, 98-100, 104-110 are rejected under 35 U.S.C. 102(b) as being anticipated by Berrang et al. (U.S. Pub. 2002/0019669 hereinafter "Berrang") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berrang.

4. Berrang discloses a hearing aid/cochlear apparatus that comprises a housing adapted to abut the patients bone (Figure 6). Berrang further discloses that the housing can be made out of ceramic (¶¶ 23, 25), and includes components located within the housing (2), and an osseointegrating protuberance that extends from the housing into the bone (¶ 22). Berrang further discloses that the device is a tissue-stimulating device (Figs. 1-6; ¶ 77).

5. Berrang discloses that the implantable device is configured, to be secured to the mastoid portion of the temporal bone in the tissue surrounding the skull (Fig. 3-6).

Berrang further discloses that the fixation device is a threaded screw and is capable of being removed after osseointegration (§ 22).

6. Regarding claim 106, Berrang further discloses that the housing is coated with a medical grade silicone (§ 69).

7. Regarding claims 108-110, Examiner notes the limitation “configured to be placed in direct contact with but not within the bone and further configured to gradually sink into the bone during osseointegration of said protuberance”, is only functional language and only requires the capability to so perform. Here the titanium screws are capable of being positioned adjacent the bone and are further capable of sinking into the bone during osseointegration.

8. In the alternative, Berrang discloses that it has a housing made out of ceramic and protuberances made out of titanium, but Berrang fails to disclose that ceramic is non-osseointegrating and titanium is osseointegrating. However, the Applicant's specification discloses that ceramic is a non-osseointegrating material and that titanium is a osseointegrating material (Applicants Spec. §35). Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the device to allow for replacement of the device while still allowing for osseointegration of the screws, as it was known in the art that titanium promotes bone growth and ceramics do not promote bone growth.

9. Claims 5-6, 21-23, 94-96, 101-103 and 112-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang as applied to claims 1, 93 and 98 above, and further in view of Håkansson (U.S. Pat. 6,840,919).

10. Regarding claims 5-6, 21-23, 94-96, 101-103 and 112-113, Berrang discloses the claimed invention as described in detail above, except for the elongated flanges that hold the disposed protuberances at opposing angles. Håkansson teaches that it is known to use flanges and anchoring devices that are disposed at an opposing angle that is approximately 85 degrees and in the same plane as set forth in Figures 1 and 2 to provide anchoring means for the implantable device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hearing aid as taught by Berrang, with flanges and multiple anchors disposed in the flanges at opposing angles as taught by Håkansson, since such a modification would provide the predictable results of a hearing aid with strong anchoring means for providing increased hold and more surface area for osseointegration.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims arguments filed 3/25/08 have been fully considered but they are not persuasive.

12. Regarding the rejection of claims 1-2, 4, 7-9, 14, 20, 24, 27-28, 30-31, 89-93, 98-100, 104-110, Applicant argues that Berrang does not teach a device that has an exterior surface adapted to prevent osseointegration. The Applicant points out that in one embodiment the ceramic housing is encapsulated to hermetically seal the device thus the devices exterior is not ceramic and thus does not prevent osseointegration.

The examiner respectfully disagrees. Berrang in paragraph 25 specifically points out that the entire housing can be made out of ceramic that is laser, ultrasonically or electrically welded making a hermetically sealed device. Thus, the exterior of the device is comprised of ceramic and thus it prevents osseointegration. It is noted that in the embodiment with the ceramic housing, the seams need to be coated with titanium to weld, however, the external surface is still ceramic and prevents osseointegration. Further, the claim states that the housing only requires an outer surface that prevents osseointegration and not that the entire external surface of the device prevents osseointegration.

13. Regarding claims 5-6, 21-23, 94-96, 101-103 and 112-113, the Applicant argues that Håkansson does not disclose or teach varying the opposing angles between the longitudinal axes of the protuberances and the implant axis. The Applicant further argues that Håkansson does not disclose, teach or suggest that varying the opposing angles is a means to effect a permanent or removable implantation. The Examiner respectfully disagrees. Håkansson teaches the structure of the claims as showing in Figures 1 and 2. It is noted that the claims requires opposing angles that are approximately 85 degrees. The structure as shown in Figures 1 and 2 shows opposing angles that are approximately 85 degrees. Regarding the Applicants arguments that Håkansson does not disclose, teach or suggest that varying the opposing angles is a means to effect a permanent or removable implantation, it is noted that the claims are directed toward a device and the prior art of Håkansson discloses the structure as

defined by the claims. It is further noted that the intended use of the device does not patently distinguish the claims over the prior art.

### ***Conclusion***

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berrang et al. (U.S. Pat. 6,516,228), De Rowe (U.S. Pat. 6,042,380), Dugot (U.S. Pat. 5,738,521), Gilman (U.S. Pat. 5,176,620), Jeffcoat et al. (4,333,469) – All discuss the bone growth properties of titanium.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./  
Examiner, Art Unit 3762

/George R Evanisko/  
Primary Examiner, Art Unit 3762